Chapter 13 510 (K) SUMMARY

510 (k) SUMMARY

Actherm Digital Clinical Thermometer ACT 2000, ACT2010, ACT2020, ACT 2000+, ACT2010+, ACT2020+

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Identification:

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Contact Person:

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Date Summary Prepared: 20 July 2000

Manufacturing Site: Actherm Medical Corp.

103 Kengzi Duan, shenshan Gong Lu, Long Gang Qu

ShenZhen, GuangDong, CHINA

Device Name:

Digital Clinical Thermometer Classic Type and Hypothermia Type

Trade Model Name:

Actherm Digital Clinical Thermometer ACT 2000, ACT2010, ACT2020 ,ACT 2000+, ACT2010+, ACT2020+

Classification Name:

Clinical Electronic Thermometer (per 21 CFR 880.2910)

Predicate Device Information:

MicroLife Instrument Co., Ltd.
Digital Pen-type Thermometer Model MT 1691
510 (k) number is K851146.

Device Description:

Actherm Digital Clinical Thermometers (Models ACT 2000, ACT2010 , ACT2020 ACT2000+, ACT2010+, ACT2020+) are electronic thermometers using a thermistor as the temperature sensor. The sensor's electric signal is then calculated and displayed by an ASIC (Application Specific IC). These thermometers display the temperature decimal. Models ACT2000, ACT2010, ACT2020, ACT2000+, ACT2010+, ACT2020+have the same indication for use. However, appearance difference exists between 2000 ,2010 and 2020 . Meanwhile, "+" indicates difference measuring range of IC design.

The digital thermometer comprises: a thermistor for temperature sensing ,a reference resistor for comparing the resistance of the thermistor, a buzzer for sounding effect , an ASIC and a LCD display for calculating and displaying the target temperature digitally which the thermistor is immersed.

The system uses a 1.5V DC battery for the power supply and the battery power is automatically checked by the microprocessor and displayed in LCD if the battery is exhausted.

Intended Use:

Actherm Digital Clinical Thermometer ACT 2000, ACT2010, ACT2020, ACT2000+, ACT2010+, ACT2020+ have the same intended use as the predicate device.It is indicated for use in the measurement of oral , axillary and rectal temperature. Actherm Digital Clinical Thermometer ACT2000, ACT2010, ACT2020 ,ACT2000+, ACT2010+, ACT2020+ are intended for use by all. Use of infants or pediatric patient population shall be under adults' surveillance. Actherm Digital Clinical Thermometer ACT2000 , ACT2010 , ACT2020 ,ACT2000+, ACT2010+, ACT2020+ are to protect safety and health of users , patients, and where appropriate, of other people.

Technological Characteristics:

Actherm Digital Clinical Thermometer ACT2000, ACT2010,ACT2020, ACT2000+, ACT2010+, ACT2020+ have the same mode of operation, design principle , and biological specifications as the predicate device. For series variants, appearance difference exists between 2000 ,2010 and 2020 . Meanwhile, "+" indicates difference measuring range of IC design.

Comparison to Predicate Devices:

The Actherm Digital Clinical Thermometer , Models ACT2000, ACT2010, ACT2020, ACT2000+, ACT2010+, ACT2020+ are substantially equivalent to the following digital thermometers. Digital Pen-type Thermometer Model MT 1691 It's 510(k) number is K851146.

The Actherm Digital Clinical Thermometers are similar in design and intended use to the predicates differing only in measurement range, function of memory , storage temperature, outlook and battery life. All products use the same temperature sensing element— a thermistor, an LCD display, ASIC, a buzzer and a 1.55V battery.

Performance Data:

Actherm Digital Clinical Thermometers ACT2000, ACT2010 , ACT2020 ,ACT2000+, ACT2010+, ACT2020+ meet the ASTM Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature (ASTM E1112-86) , as well as IEC 601-1 and IEC 601-1-2 requirements .Bench testing confirmed accuracy, precision and repeatability measurements specified in the labeling. For all body contacting materials, analysis is made that the identical materials have been used in other legally marketed devices under the same use conditions (See Chapter 8 Safety and Effectiveness Evaluation and Chapter 10 Biological Compatibility Report).

Substantial Equivalence:

The Actherm Digital Clinical Thermometer, Model ACT2000, ACT2010, ACT2020, ACT2000+, ACT2010+, ACT2020+ have the same intended use, principles of operation , and similar technological characteristics as predicate devices. Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Actherm Digital Clinical Thermometer, Models ACT2000 , ACT2010, ACT2020 ,ACT2000+, ACT2010+, ACT2020+ are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2001

Actherm, Incorporated
C/O Mr. Mark Job
Responsible Third Party Official
TUV Product Service, Incorporated
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K010238
Trade Name: Actherm Digital Clinical Thermometer, Models ACT2000, ACT2010, ACT2020, ACT2000+, ACT2010+, ACT2020+
Regulatory Class: II
Product Code: FLL
Dated: January 13, 2001
Received: January 23, 2001

Dear Mr. Job:

This letter corrects our substantially equivalent letter of February 6, 2001 regarding the Trade Name.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA)

may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note that the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010238

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510(k) Number (if known):_____

Device Name: **Electronic Clinical Thermometer**

Indications For Use:

The device is an electronic clinical thermometer using a thermistor to detect the human body temperature oral, axillary or rectal. The device is intended for medical professionals and for home use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

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Patricia Cusumbo

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010238

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